

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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: PHILADELPHIA, PA  
ZOLOFT :  
(SERTRALINE HYDROCHLORIDE) : September 1, 2015  
PRODUCTS LIABILITY LITIGATION: 3:27PM

TRANSCRIPT OF DAUBERT HEARING DAY 2  
BEFORE THE HONORABLE CYNTHIA M. RUFÉ  
UNITED STATES DISTRICT JUDGE

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I N D E X

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COLLOQUY

3

WITNESS: NICHOLAS JEWELL

Direct Examination by Mr. Zonies

3

1 Q. That new data while it was reported as a 1.0 when it  
2 includes the Alwan data that necessarily the new data that was  
3 not included in Alwan would've had a different effect?

4 A. Well, here it was a little different from Jimenez-Solem  
5 because they did provide in their supplement the ability to  
6 break out the data see the new data and directly compare it.  
7 And the new data showed a stronger, not very strong, but a  
8 stronger association than originally in Alwan. This is just I  
9 think for -- this is not for all cardiac this is just septal  
10 defects. And refuse was the only paper that I've seen that  
11 didn't actually talk about all cardiac and that's because  
12 Alwan didn't find it interesting and the original and they  
13 only focused on results from the earlier paper in this case.

14 Q. So, I put up there 1.2, 1.3, did you actually do that  
15 calculation at some point?

16 A. I did.

17 Q. And do you recall what it was?

18 A. My memory is it's 1.22, but I hate to go by memory.

19 Q. Dr. Jewell that -- when you're examining the  
20 associations your primary focus as you said was on Zolofit all  
21 cardiac outcomes and this is a [indiscernible] that captures  
22 those outcomes; is that right?

23 A. That is correct.

24 Q. And it has Cornum, Wemacher [ph] and it says next To  
25 Wemacher severe CHD. Did Wemacher also have a CHD finding

1 over a cardiac heart defect finding and a severe cardiac heart  
2 defect finding?

3 A. Yes. Wemacher's I think the only paper, there are  
4 other papers who talked about doing this which has said let's  
5 not look at all cardiac heart defects, because there's a  
6 concern about some of those are reported differentially if  
7 you're exposed or not, because of a variety of reasons we  
8 could discuss.

9 So, one way to get around detection bias is to focus on  
10 severe cases which are likely to be detected under all  
11 circumstances and.

12 THE COURT: I'm sorry.

13 THE WITNESS: That's okay. That's what Wemacher  
14 did. They did report had results for all cardiac defects and  
15 then they looked at the results for the severe. So, this  
16 slight that's just popped back again has the one with the  
17 severe CHD in it.

18 BY MR. ZONIES:

19 Q. And then you've also -- and I want to be clear Dr.  
20 Jewell, you reported all of the outcomes for all of the  
21 studies; right? You're not trying to duplicate and make it  
22 look like you're trying to slide one by on the judge; are you?

23 A. No. Again, it's important to pointer out that Cornum,  
24 Jimenez-Solem and Petersen are all there near the top.

25 They're all Danish and there is some overlap. I don't want to

1 go over the territory again. So they performed less  
2 replication because you have to do the kind of discussion I  
3 just gave. You have to think about it a little bit more  
4 carefully.

5 And Reese Collen [ph] and Collen are in there at the  
6 bottom and they're, you know, Collen is really superseded by  
7 the Reese Collen they don't differ that much, but once you  
8 take that into account, this is all of the reports and all the  
9 literature that is important.

10 Q. And is there a reason you wouldn't want to look at all  
11 it and try to understand it?

12 A. No. I always want to look at it all.

13 Q. You also, Dr. Jewell report separately for septal  
14 [indiscernible]; is that right?

15 A. Yes, and here you can see the confidence in those  
16 getting whiter because, of course less, septal is a  
17 subcategory of all cardiac so you'd expect less precision, so  
18 that's what you see.

19 Q. Did you decide to create these all septal categories or  
20 this is what's provided in the scientific literature?

21 A. No. These are all provided in the original papers  
22 noted there.

23 Q. Dr. Jewell, when you're looking at the outcome of all  
24 cardiac and this is what you see, why do you both to look down  
25 at septal defects?

1 A. Well, I discussed this in my report and it's a  
2 conundrum that faces statisticians from an epidemiology from  
3 day one. You want to look at the association between an  
4 exposure and an outcome and if the outcome's pretty bad and  
5 some of these outcomes are bad, pretty bad or if the outcome  
6 is cancer that's pretty bad. It's fortunately often quite  
7 rare and these birth outcomes do not occur fortunately one out  
8 of every two births, otherwise, we'd have lots of them and we  
9 could get very, quite narrowly into specific subcategories,  
10 because there'd be a lot of them available for study that  
11 already all cardiac birth defects are not that common so you  
12 have to get a lot of woman and we saw numbers this morning, a  
13 million woman to get data. You have to look at a lot of  
14 pregnancies to even get close to some information that's  
15 reliable on a big category like all cardiac outcomes. That's  
16 why statisticians and epidemiologists have always done that of  
17 grouping outcomes that they think are reasonable, I wouldn't  
18 do it, I'm a statistician, but you get the expert when the  
19 first studies at Twenty Hills, first studies of lung cancer  
20 came out, we know there are different kinds of lung cancer,  
21 asbestos and smoking actually tend to raise the risk of  
22 slightly different kinds of lung cancer.

23 To you and I it's just lung cancer, but to the people  
24 who understand pathology of the lung there are different kinds  
25 of lung cancers, but when they did those studies, early

1 studies of smoking, because it was hard, an observational  
2 studies to get definitive information that would change policy  
3 they lumped them all together, because they needed sufficient  
4 data. And that choice is almost always there in every  
5 epidemiologic study, what's the outcome? How do you group  
6 them? Where -- if you go too big you have a chance of putting  
7 in [indiscernible] outcomes which have nothing to do with  
8 exposure and that will weaken your ability to see association.

9 On the other hand, so you get bias, basically and  
10 dilution. On the other hand you get very precise and say, I  
11 really think it's this specific heart defect where the problem  
12 is and you only get that specific one occurring one in 10,000  
13 pregnancies you're going to end up with no data. So, how do  
14 the epidemiologist resolve that problem?

15 They get the experts together, they decide these bigger  
16 subcategories and they essentially draw that line of where  
17 they think it makes sense. Some of the authors in here have  
18 sufficiently small studies that they didn't think it made  
19 sense to go -- even to report subcategories and they had rules  
20 about that, but all of them had sufficient cases to report  
21 about all cardiac, as we've already discussed. That's the  
22 only reason I use that essentially as a category that made  
23 sense.

24 Now, do you want to look at the subcategories? Sure,  
25 suppose I'd seen a large ratio for all cardiac of two and then

1 you come along and say, I have a client and it's a cardiac  
2 defect, but it's this very specific one, a TGA, let's say,  
3 transposition of the great arteries. I say, oh, well, I'll go  
4 look at the data. There's hardly any data reported. It  
5 occurs very rarely. I think only one paper reported  
6 separately on TGAs, there's no information. Are we lost? No.

7 Suppose there had been data on TGA as a subcategory,  
8 remember, I said all cardiac idea seen in a [indiscernible] of  
9 two, but in TGA I saw consistently odds ratio .9. Well that  
10 would tell the statistician even though in the big category it  
11 looks like something is going on, it doesn't seem to be  
12 mirrored in the subcategory. The subcategory seems to be  
13 something that's in there, but there doesn't seem to be  
14 anything going on.

15 So a statistician will want to look at the big category  
16 to get precision and then look at the pattern of the  
17 relationship in subcategories to see if there's any, that seem  
18 to be pointing in a quite different direction and that's why I  
19 looked at the subcategories to the extent they were reported.

20 Q. So, Dr. Jewell, let's take a look at that. This is  
21 your cardiac outcomes with outcomes of 3, 2.8, 2.7, 2.36,  
22 1.74, 1.5 and as you start to go into the subcategories you  
23 still see in septal consistently increased risk; right?

24 A. Yes.

25 Q. And if you look at reported differently here, above the



1 line would be increased risk, below the line is decreased risk  
2 for ASD as you get more refined atrial septal defects,  
3 ventricular septal defects, ABSDs, are you seeing any sort of  
4 a consistent patten even if you go to the other cardiac de  
5 fact which captures hypoplastic left heart, contrology of  
6 [indiscernible] RVOT, LVOT, all above this line positive  
7 associations. What does that tell you about the heterogeneity  
8 or not of these various cardiac outcomes?

9 A. Well, to do it justice, of course you have to spend  
10 some of the hours spent looking at it that in brief if you  
11 think of those flores plot [ph] flashing before your eyes all  
12 cardiac then the subcategory of septal then, a subcategory of  
13 let's say atrial septal defects or ventricular septal defects,  
14 the pattern of the flores plot looks the same as you go down.  
15 In other words what I'm looking for is there's a subcategory  
16 here which doesn't show any increase in risk systematically.  
17 It looks different from the big flores plot and that isn't  
18 apparent in this case, but that's why we look at it.

19 You have to recognize when you go down to the  
20 subcategories everything is more variable because there's less  
21 information, but even with that where you'd expect the results  
22 to bounce around a bit, I think you see enough here to see  
23 that there isn't a subcategory here that's demonstrably  
24 showing a different pattern of association than what you saw  
25 in the catchall all cardiac subgroup.

1 Q. Dr. Jewell, when you, after you examined the  
2 associations for pulling them out and looking for these  
3 generalizable thoughts about the subcategories did you then  
4 assess the -- in your methodology assess these associations  
5 for whether or not they were simply the product of chance ren  
6 variation?

7 A. Yes, there's been many times in my life where that's,  
8 when the story is stopped, because the data just doesn't look  
9 like it's sufficiently strong to be anything other than chance  
10 and that happens.

11 Q. When we're looking at these associations are a function  
12 of for example ren [ph] variation or systematic variation can  
13 you help us understand what that means, in other words, this  
14 is a 3.6 outcome here, so would bias and confounding if it  
15 were in play to make that disappear how big of an effect would  
16 you be looking for?

17 A. Well, we can quantify that, you would have to have a  
18 very, another risk factor confounding factor for example that  
19 would be as strongly related to the outcome as the 3s  
20 mentioned there to completely wipe that out.

21 Q. So, something going on in confounding or bias would  
22 have to be three times more prevalent if that's the rights to  
23 the -- I knew you'd say that. So, it would have to occur,  
24 have a three times impact on the odds ratio.

25 A. Do you want to restate that question before I give you

1 a grade?

2 Q. Yes. Could you restate the --

3 A. Yes. For confounding, we know that -- let's just take  
4 an odds ratio of three, if that is explainable by a  
5 confounding, so the true odds ratio is one, once you adjust  
6 for this hypothetical confounding factor. That hypothetical  
7 factor in itself has to have an odds ratio of at least 3. And  
8 it also has to have a relationship to, in this case Zolofit  
9 that's the exposure you're interested in. That's also a  
10 strong as three, so there isn't just, you can't just sprinkle  
11 a little confounding and wipe out the three, that's was the  
12 argument behind Bradford Hills first criteria, the strength of  
13 association.

14 It's -- when we saw an odds ratio of 10 for lung cancer  
15 and smoking the arguments of confounding went away and there  
16 were very, very strong arguments of confounding presented not  
17 only by industry at that point, but also by preeminent  
18 statisticians that thought smoking and lung cancer was just  
19 confounded, there was nothing to do with smoking, but when the  
20 size of it became apparent by Hill's work and by Dull's [ph]  
21 work then it became impossible to explain by some unknown  
22 confounder that we occasionally see that language, Mr. Cheffo  
23 put it out, but it's an unknown confounder.

24 Well, that's not, it's not so unknown it's got to be,  
25 it's a pretty strange confounder if it's that big and it's

1 still hiding from us.

2 Q. So, Dr. Jewell when assessing chance it is and I think  
3 you've said important, one of the factors that's important is  
4 statistically significant results.

5 A. Well, if there's nothing that's significant at all  
6 anywhere and all these results are just -- if that's the plot  
7 of all the associations they've all been sort of some to the  
8 right of one, some to the left of one, I would have just told  
9 you my report and you probably wouldn't have hired me, but  
10 that would've been the truth and that's where it would've  
11 gone.

12 So, if there was nothing going on, there's nothing  
13 going on. And that just happened to me probably more times  
14 than I found something going on, it's just part of life.  
15 But -- so that's the first sort of sign of [indiscernible] it  
16 seems to me. Let's not waste your time and my time if it's  
17 apparent to me that there's really no evidence one way or the  
18 other.

19 Q. And here did you find that there was evidence?

20 A. Yes.

21 Q. And one of the things that I discussed in my opening  
22 was Bonferroni context, is this something that you actually  
23 support doing to test this question?

24 A. I do support it in the context of the individual  
25 studies. If you take an individual study and you go fishing

1 for associations or what's the word that was used a little  
2 bit -- torturing, if you torture the data by looking at every  
3 possible association, gee, if you have red flowers in your  
4 front yard, you tend to have a heart attack and you find that  
5 association. If you look for enough you'll find them, that's  
6 what multiple comparisons are about, because it's like double  
7 jeopardy, it's triple, you're just trying -- you're just  
8 random -- you're sort of picking at straws, clutching as  
9 straws to find an association in a single study. That is a  
10 fallacy and we recognize it, we're particularly sensitive of  
11 it now with genetic studies in a single population, because  
12 there's 30,000 genes to look at to see if they're associated  
13 one by one with an outcome.

14 So, you have to have very string stringent controls  
15 then although, it's like kind of what I would call fishing for  
16 associations there. And Bonferroni was a way to adjust the P  
17 value to make those stringent criteria within a single study.  
18 And you can do it here Jimenez-Solem is the one major study  
19 which survives that kind of criterion. The others don't, big  
20 surprise, because we've already said time and time again these  
21 studies individually find it very hard to be definitive  
22 because there isn't a huge amount of data, so you wouldn't  
23 expect single studies really to show significance necessarily  
24 always which we've seen they don't, let alone surviving even  
25 stronger criteria, it doesn't make sense, and in fact, when

1 you go to looking at multiple studies the issue of multiple  
2 comparisons essentially dissipates for reasons I outlined in  
3 the report.

4 Q. And you've reviewed some of the e-mails I'm not going  
5 to go through these in detail, between other epidemiologists  
6 who were involved in these types of studies including Dr.  
7 Mitchell, Dr. Hernandez-Diaz, Dr. Greenland discussing the  
8 importance of significance or not related to a P value. Do  
9 you generally agree with these statements about slavish  
10 worship to that dichotomy?

11 A. Yes, I think in fact all the e-mails that I saw about  
12 this issue we all agreed accept for the editor at the New  
13 England Journal who agreed but said the rules are I've got to  
14 do something different. And then there's little e-mails about  
15 how could this editor believe this is crazy, but still make us  
16 do it, but, yes, but avenue statistician and epidemiologist in  
17 those e-mails agreed entirely that the whole thing was not  
18 relevant really.

19 Q. If you limited your inquiry in this case, Dr. Jewell,  
20 solely to the statistically significant results, would there  
21 be any results to the left of one?

22 A. No. As I said in my report there are some studies that  
23 show a negative association where the odds ratio comes in less  
24 than one, so the risk seems a little bit lower in woman  
25 exposed to Zoloft, but none of those achieved statistical

1 significance. And in some sense the slight here points out  
2 why one shouldn't limit to significance and if I had, how I  
3 would've been excoriated by everyone in sight, because this is  
4 all I would've talked about were these studies and everyone  
5 would've been unhappy. You would've been unhappy for  
6 different reasons than Mr. Cheffo, but I think both of you  
7 would've been unhappy with me, I wouldn't have done my job  
8 because you shouldn't and that just tells me that you know  
9 already you've got to look at all the evidence, because in the  
10 law you always look at all the evidence you don't just look at  
11 the significant clues, you look at all the evidence. And some  
12 of it isn't as important as others and there's no question  
13 that's true some of these studies are not as important as  
14 others, but you got to look at it all.

15 Q. Now, there's a continuing, it's here in the  
16 [indiscernible] by Pfizer for the past years, Dr. Jewell that  
17 apparently you believe an outcome like this one in -- Alwan,  
18 that you believe an outcome like this in Alwan the bottom last  
19 one that is to the left of one and crosses one on the upper  
20 bound somehow shows an increased risk; do you believe that?

21 A. No. I was quite explicit in my report that that study  
22 shows a decreased risk, it's inconsistent with my opinions.  
23 There's no question about that.

24 Q. That study result right there is totally inconsistent  
25 with what you ultimately proved.

1 A. It's below one, that's correct. Though you can see  
2 what I do point out in my work how precise is that known,  
3 because that's going to be important. In that one you can see  
4 specifically is very imprecise. The confidence interval goes  
5 from .1 to I can't really read it because the scale is never  
6 two or something, so it's very imprecise, but it does not  
7 support causation in this case, there's no question about  
8 that.

9 Q. Now, is there something about this upper bound or some  
10 portion of this upper bound that you do at least talk about  
11 being not incompatible?

12 A. Well, if you take the one, let's go to the first one  
13 that sort of drops below one if you can point to that, that  
14 one right there. Yes, so there's one that's .9 something, is  
15 an odds ratio and the data says there's less risk in the  
16 Zolofit exposed women in that study. So, I can't use that to  
17 say Zolofit causes a birth defect, that would be crazy; right?

18 Q. I think so?

19 A. That would be crazy, somebody said nuts. I'd be nuts.  
20 But look at the length of that confidence interval. Now, I  
21 know it goes way down to the left, that's no one in this  
22 courtroom believes that Zolofit has an odds ratio of .2 or .3,  
23 but you're 5 times less likely to have a cardiac. In fact  
24 Pfizer doesn't believe that, they'd be selling the drug to  
25 protect you from a heart defect anymore than people believe



1 the very right end of the confidence interval reaches five or  
2 six.

3 So, no one believes those end points, I understand  
4 that, but if you look at the imprecision in that study while  
5 it does not support my conclusions it doesn't really  
6 contradict them in and of itself because it's quite compatible  
7 with an odds ratio of and there wasn't enough data in that  
8 study to precisely nail down that two was ridiculous. So  
9 that's all I'm saying. I'm not saying supportive, I'm just  
10 saying it doesn't flatly contradict that and that's true of  
11 many of those that are down there as you can see half of them  
12 down there below one the confidence band on the right goes  
13 quite far up into the range of increased risk.

14 I mean if you would just go back to that slide for a  
15 second, I don't want to prolong things, but if you said to me,  
16 can you write a report that says the odds ratio for Zoloft and  
17 cardiac defects is .3, do we have evidence that there's a  
18 three-fold decrease in risk?

19 So, here's the data .3 if you can run your pointer up  
20 there, cuts may be 2 at most, maybe it gets that third one.  
21 There's no one in this room would believe that. Even though  
22 there's no -- a few of them are significantly different  
23 from .3, some of them aren't as we just said, but the  
24 preponderance of the evidence makes it clear to everyone.

25 Now, we're not in the quite as crystal clear situation

1 when we're talking about one here, but that's the way you've  
2 got to do it and in Hill's language, you have to say what is  
3 the reason for this pattern? It's clearly not symmetric.  
4 What is the reason here and is there -- here's his language,  
5 is there any other way of explaining the asymmetry of that  
6 plot? Or any other answer equally or more likely than cause  
7 or effect and that's what the rest of the report goes through.  
8 Is there another reason why we're seeing these studies slanted  
9 to a positive association.

10 Q. And that's what you get into next, right, is systematic  
11 variation --

12 A. Right.

13 Q. Bias or confounding? In your own words you don't stop  
14 there and say, yes, well, jeez it was all -- looks like there  
15 was more on a risk, but you actually go in and then say is  
16 something else causing that?

17 A. Yes, and many of the authors have raised in their  
18 limitations of their work, some of the biases that can -- may  
19 have distorted what we're see, and so we've got to pay  
20 attention to that.

21 Q. And one of the main ones -- you looked at many in your  
22 report; is that right?

23 A. I did. I did and confounding in general do women  
24 Zolof smoke more or are they more obese, these other risk  
25 factors for cardiac of birth defects, I want to point out,

1 just before that was very important to look at that all the  
2 authors tried their best, some more successful than others.  
3 The flores plot we just had all of the results adjusted for  
4 all confounding that those authors did.

5 These are not the crude results. These are already  
6 de-biased in some sense by getting rid of all the confounding  
7 that the original authors were able to do.

8 Q. Well, and to put a fine point on that Dr. Jewell, the  
9 Huybrechts' number for all cardiac is I think 1.09 here.

10 A. Yes.

11 Q. And not significant. If you had chosen to try to get  
12 one by on everybody here you actually would've put in the  
13 Huybrechts' crude which would be 1.27 and it would actually be  
14 up here as statistically significant; right?

15 A. That's correct. So it moved on. And that was  
16 adjusting for confounding not only by a lot of these factors  
17 like smoking it was also adjusting for this confounding by  
18 indication by adjusting for whether the women had a diagnosis  
19 of depression or not.

20 So, I just want to be clear that flores plot has taken  
21 out as much as I can of those biases to the extent they were  
22 reported by the authors.

23 Q. So, the Huybrechts for example would've gone from 1.27  
24 statistically significant in its crude down to its 1.16 when  
25 they do the depression restricted, but you even reported the

1 propensities for 1.09.

2 A. Yes and that was just adjusting for other factors that  
3 the women -- other, many, many other factors that the women  
4 had to try and remove their impact on the question.

5 Q. So, had we chosen to put the crudes in here for  
6 example, you could imagine this whole thing would actually --

7 A. It would've shifted to the right. Not always, but by  
8 in large.

9 Q. Now, confounded by indication I'm not going to go  
10 through each of these Dr. Jewell, because again, these are in  
11 your report that there were no studies demonstrating that  
12 depression in and of itself causes cardiac malformations.

13 And then the other various techniques that the authors  
14 have used to determine whether or not it's depression  
15 including looking at other antidepressants, this is all in  
16 your report; correct?

17 A. It's all in my report, yes. I looked at that careful.

18 Q. But, you -- and Jimenez-Solem, this is also in your  
19 report attempted to do this through this pause group analysis;  
20 is that right?

21 A. Correct.

22 Q. And you've mentioned that the Knutsen [ph] article, I  
23 believe in your report which discusses why that pause group  
24 may actually have this increased risk. Could you talk about  
25 your thoughts on the Jimenez-Solem pause group, first of all

1 about the fact that it's all SSRIs and then what else you  
2 think of that analysis?

3 A. I actually don't believe I did comment on Knutsen, Yen  
4 about the paper at the time I wrote the report, but I wrote  
5 the same argument that Knutsen actually wrote about later and  
6 that was that the definition of being paused in Jimenez-Solem  
7 was that you had to be taking an SSRI up to a certain time  
8 period several months before conception, at which point you  
9 did -- had no more prescriptions, so you paused.

10 And then you had to pick it up again, after a  
11 certain -- within a time period after the pregnancy had ended.  
12 There was a time interval at the end. And I said in my  
13 original report that gave me some concern, because of the fact  
14 that that might introduce a bias that women who suffered any  
15 form of birth defect or any complication in their pregnancy  
16 might be more likely to go back on antidepressants and that  
17 that would bias the results, of course, of Jimenez-Solem and  
18 that's the same reason that Knutsen independently wrote about  
19 that I didn't know when I wrote the report.

20 Q. And how would that bias the results? Why would that  
21 make it seem like there's more risk in that pause group?

22 A. Because it means that you're more likely to get into  
23 the pause group if you've had a heart -- not a heart -- any  
24 defect. So, we'll raise, artificially raise the rates of  
25 defects in the group. And they, Jimenez-Solem points out and

1 it was pointed out this morning by Mr. Cheffo that this pause  
2 group had an increased risk. And that's one possible  
3 explanation, not necessarily of the entirety of the increased  
4 risk, but why it may be overstating the risk of a true pause  
5 group, because you've got this bias and the way you've defined  
6 the pause group.

7 Q. And the fact that it's looking and only reporting on  
8 all SSRIs does that give you pause?

9 A. Yes, because at the beginning of my report and what  
10 we've discussed earlier I was at pains to try and use Zoloft  
11 specific information unfortunately Jimenez-Solem pause group  
12 is a group of women who took any SSRIs, not women who took  
13 Zoloft and then paused. Now, there had to be some in there  
14 who were Zoloft, it would be rather fewer, because we do know,  
15 from Jimenez-Solem the fraction of the women exposed to SSRIs  
16 before pregnancy who were Zoloft specific, but they don't  
17 report in the pause group how many were Paxil, pause Paxil  
18 users, pause Paxil users or pause Zoloft users.

19 So I couldn't compare the pause Zoloft users to the  
20 non-pause Zoloft users. I did have the data and Jimenez-Solem  
21 talks about the data for Zoloft-exposed women who continued to  
22 you it, but when you compare it back to a pause group it's not  
23 Zoloft paused only, it's a mixture of other women.

24 Q. And is that in an analysis that given the data you had  
25 you thought would be of interest?

1 A. Well, the whole point of Jimenez-Solem was to try and  
2 pull out this pause group and see if they were at an increased  
3 risk and we've talked about why they might be artifactually  
4 because of this definition of you had to go back on the SSRI  
5 and Zoloft after the pregnancy. Nevertheless this was at the  
6 core of Jimenez-Solem's argument about confounding by  
7 indication.

8 The argument I think I'm not -- I'm using their words  
9 as best I can. The argument is that if the pause group is  
10 still at increased risk compared to unmedicated depressed or  
11 unmedicated women, depressed or not it can't be the drug,  
12 because they're not taking it, they paused. That was the  
13 whole beauty of the Jimenez-Solem attack on the question. It  
14 was creative, they had pharmacy records, they had the ability  
15 to get the timing from pharmacy records. So, that was the  
16 whole point.

17 Unfortunately in my view they did that, they looked at  
18 the pause and they said they're at increased risk, but they  
19 didn't complete the loop which is yes, but are they at  
20 increased risk compared to the ones who didn't stop?

21 If you really had an ideal experiment, I forget the  
22 nice word Mr. Cheffo used exquisite experiment, you would take  
23 a group of women, you want it, the trouble plaguing this field  
24 is who do you compare Zoloft users, pregnant Zoloft users to?  
25 And initially they would compare them to any women having a

1 pregnancy and then people said, oh, wait a minute the women  
2 who suffer from depression aren't really comparable. You're  
3 comparing an apple and orange so, then, you know, then papers  
4 like Huybrechts, they try to restrict that we're going to look  
5 at depressed women some who take Zoloft and some that don't.  
6 But still a little bit -- Zoloft users are not necessarily the  
7 same Paxil users or they're not the same as somebody using  
8 another antidepressant or someone who's depressed that isn't  
9 taking a drug.

10 So, the goal of an epidemiologist is to try and get how  
11 do you pick those controls? The comparison group? What you  
12 would ideally like is a group of Zoloft users to a pregnancy  
13 that's your exposed group and then have another group of women  
14 who are identical in all regards who didn't take Zoloft,  
15 everything else would be the same.

16 The only way we know how to achieve that  
17 methodologically is to randomize. So, you will take Zoloft  
18 users and you'd randomly pick half of them when they conceived  
19 and said you can't take Zoloft anymore.

20 If we had that experiment that would be exquisite,  
21 because there could be no difference between the groups except  
22 that they didn't get -- one half of them didn't get exposed.  
23 We can't do that and people have judged that's not ethical for  
24 obvious reasons. The closest thing in all of these studies to  
25 getting to that exquisite experiment that all statistician and



1 epidemiologists want to do is this paused analysis. And you  
2 want to therefore say, okay, these women were identical going  
3 into conception, they were all taking Zoloft. Some of them  
4 stopped taking it and now we have this ability to compare  
5 those who continued and those that don't and see what the  
6 results. And Jimenez-Solem didn't actually do that, they  
7 compared both groups to the women not taking any drug, but  
8 when you do the direct comparison you get the 60 percent  
9 increase in risk which can't be purely then, so the  
10 confounding by indication hasn't completely eradicated this  
11 fact that women who stayed on it suffered for more cardiac  
12 defects than women who didn't. And here's the data. There's  
13 that 1.6, 1.59 to be precise.

14 Q. Your Honor, I'm about to go into a new area.

15 THE COURT: Nice area to take a break. Let's  
16 take ten minutes.

17 (Whereupon there was a recess in the  
18 proceeding from 4:01 p.m. to 4:17 p.m.)

19 DEPUTY CLERK: All rise. Court is now in  
20 session The Honorable Cynthia Rufe now presiding.

21 THE COURT: Everyone please be seated.

22 MR. ZONIES: Your Honor, I'm not sure what you  
23 want to do in timing. I think I probably have in truth 40, 50  
24 or so to go. Dr. Jewell is here with us tomorrow as well, so.

25 THE COURT: Certainly, but if you can complete

1 your direct it would be best. We think we should keep going  
2 as long as we can all refrain from dropping our water bottles  
3 on the floor. Noise, that was me. All right. Thank you.

4 MR. ZONIES: We'll look to complete his direct  
5 tonight, Your Honor, today, whatever.

6 THE COURT: I do need though if you're going to  
7 keep using the -- we can't find this exhibit in the exhibits  
8 and it's very important to your case. We just need a copy  
9 that needs to be enlarged. Let's just say it, we need bigger  
10 letters because it's very hard to follow on any of our  
11 screens. I'm sorry that it just can't be enlarged enough to  
12 see it all at once; all right.

13 Mr. ZONIES: Absolutely.

14 THE COURT: So maybe overnight somebody can  
15 collie and enlarge it for us.

16 Mr. ZONIES: We can do that.

17 THE COURT: Thank you. All right. Please  
18 proceed.

19 BY Mr. ZONIES:

20 Q. And Dr. Jewell, I just want to while we're talking  
21 about this flores plot --

22 THE COURT: That one.

23 THE WITNESS: That's the one that's hard to see.

24 BY MR. ZONIES:

25 Q. What it -- in your methodology Dr. Jewell, where does

1 this fit in?

2 A. Well, this is really in my report a visual aid just to  
3 be able to try and put on one page, as difficult as it is to  
4 read all of the results. This is a few more than in my  
5 report, because of the new studies. So this is just a visual  
6 aid to be able to refer to it to see all in one page the  
7 whole, all the results whether in this case it's for all of  
8 them, but then the other ones for subcategories. It's just  
9 helpful as a visual device, I'm not trying to infer from this  
10 plot something quantitative. I've only referred to it this  
11 afternoon in the asymmetry of the plot which I think is  
12 apparent to everyone in the room, but other than that I'm not  
13 trying to infer anything directly from it and I've talked  
14 about why doing a meta analysis of all of those is fraught  
15 with danger, very appealing, but fraught with danger and we  
16 can talk more about that and where one might go given the fact  
17 that these studies are actually not all on equal footing, and  
18 two, show such heterogeneity.

19 Q. So, if for example Dr. Jewell is this something where  
20 you plotted these results out the first week you started  
21 working on this and you looked at this and tried to decide  
22 something today or is this something that you do to help guys  
23 like me when you're presenting your opinions?

24 A. Actually I produced this or a plot like this at the  
25 very end of writing the report. I didn't actually have it, I

1 had enough little notebooks and things laying around then at  
2 the end when I got rid of all those I are thought this -- I  
3 need something to be able to refer to and I put this in at the  
4 end of the report to sort of summarize where I thought it  
5 might be useful.

6 Q. We were talking about confounding by indication and the  
7 exquisiteness of Jimenez-Solem's pause group and some of the  
8 shortcomings of that and now idea like to talk, Dr. Jewell,  
9 about the Huybrechts analysis and in particular a more  
10 exquisite look at this data; okay?

11 A. Correct. Okay.

12 Q. There's a slide on the screen now that is the  
13 Huybrechts 2014 study entitled Antidepressant Use in Pregnancy  
14 and the Risk of Cardiac Defects. Is this a study that you've  
15 spent a great deal of time reviewing?

16 A. Yes.

17 Q. How did and as it shows on the screen, how did  
18 Huybrechts in this 2014 study define whether or not women were  
19 considered to be exposed to an antidepressant and in  
20 particular Zoloft during the critical period of early  
21 pregnancy?

22 A. Yes, so, the Huybrechts team had Medicaid data on  
23 pregnancies and then they had to merge that data with data on  
24 pharmacy records associated with Medicaid, so they had -- this  
25 was not -- the data set they had to construct basically by

1 merging data sets, once they had done that to the extent, that  
2 was done well and effectively, they then had to define what  
3 they meant by exposure, because people go on and off  
4 prescriptions all the time and so the piece that's highlighted  
5 in there with regard SSRIs they looked at the most recent, if  
6 you will, the most recent prescription of an SSRI prior to  
7 conception and they could see the number of pills that would  
8 be in the prescription and count the days and then say, if the  
9 prescription if taken as prescribed would take the woman into  
10 taking those pills during postconception count that woman as  
11 exposed.

12 Q. And so they looked at supply of in this case Zoloft  
13 over a period of weeks before conception and tried to  
14 determine if that supply would allow a woman to have the pills  
15 in a medicine cabinet essentially during the critical period  
16 of pregnancy?

17 A. Right. They did not know if the woman actually took  
18 the pills pregnancy for any person for obvious reasons, that's  
19 not recorded in the database and that's of course a weakness  
20 with pharmacy records because we know that people don't always  
21 take the medication, I bet you've not always taken your  
22 medication when prescribed. So --

23 Q. I don't need medication.

24 A. It's a problem, but that's the best her team could do.  
25 And it's somewhat similar to Jimenez-Solem had similar

1 pharmacy records.

2 Q. So, Huybrechts initial analysis that we've discussed  
3 compared, I'm showing you a slide Dr. Jewell of Huybrechts  
4 analysis with an odds ratio of 1.27 that is significant at the  
5 P value .05. Can you describe what this slide shows?

6 A. Yes, once she's classified, once her team has  
7 classified the women and the pregnancies into exposed that's  
8 the red here and unexposed and in this case removing women who  
9 were exposed to other antidepressant, so they have no  
10 antidepressant exposure at this point during their pregnancy.  
11 Then she compared the rate of cardiac defects and other  
12 defects in the red group versus the blue group, not  
13 surprisingly the blue group is huge, it swamps the red group,  
14 but nevertheless there's a lot of pregnant women exposed to  
15 Zoloft in their database 14,040 and the rates are compared and  
16 they're 27 percent higher in the red group than the blue  
17 group.

18 Q. And is that a true crude odds ratio is that what that  
19 would be?

20 A. That's a crude odds ratio. Just look at the rate of  
21 cardiac defects that are also now in this merged data set.

22 Q. And then the Huybrechts authors did a what's called on  
23 this next slide, Huybrechts analysis depression restricted  
24 comparison. Can you describe for us please what they did for  
25 depression restricted and/or and what the results were?

1 A. So to get around the idea that it's depression itself  
2 that may be contributing to a rate of defects in the exposed  
3 women and not the control in a previously light where include  
4 women who had no diagnosis of depression, had no reason to be  
5 taking an antidepressant so, that included a lot of  
6 nondepressed women to put it crudely. And so to get around  
7 that they said let's just use as the comparison group those  
8 who had a diagnosis of depression. I'm speaking somewhat  
9 colloquially you can be precise and that removed a few of the  
10 Zoloft users what dropped from 14,000 to about 11,000, but it  
11 of course reduced a huge number of the blue group and they had  
12 a -- but still had a 180,000 left and now you can do the same  
13 comparison, what's the risk of the cardiac birth defect in the  
14 red versus the blue, the Zoloft exposed to the unexposed and  
15 now it's dropped a small amount to 1.16.

16 Q. And what do you mean by its dropped a small amount?

17 A. Well, it went, I think it was 1.27 before and it  
18 dropped to 1.16 so that's important particularly since we  
19 close to one in this study for a number of reasons we could  
20 discuss. So, it's important from a statistician, you're not  
21 able if you look at the 1.27 could you flash back to that  
22 slide for a second?

23 So, the lower banned of that 1.07, 1.52, 1.16 is right  
24 in the mix there. It's hard to tell the difference between  
25 1.16 and 1.27, but nevertheless it's moved it towards one

1 that's where you ought to focus on, because that's a more  
2 homogeneous, these groups are more homogeneous now, they all  
3 have a diagnosis of depression as compared to the one in the  
4 previous slide.

5 Q. So, now, in the Huybrechts study, Dr. Jewell there's an  
6 additional I think two levels of adjustment based upon  
7 something called propensity score analysis; is that right?

8 A. Correct. That's correct.

9 Q. Can you describe for us what that means a propensity  
10 score analysis?

11 A. Well, that's complicated.

12 Q. Okay.

13 A. It's basically a method for trying to balance so that  
14 you would want, suppose smoking was a little higher in the red  
15 group than the blue group and you were worried that that's  
16 distorting the rate comparison I just talked about, so you now  
17 adjust, you really re-weight the data to make the fraction of  
18 smokers in the both group the same by re-weighting basically  
19 counting down-weighting the numbers smokers in one group and  
20 up-weighting them in the other, basically.

21 And you do that for a whole bunch of [indiscernible]  
22 they actually did it for over 200 characteristics of the women  
23 and you need some massive software and some coding and you --  
24 but the basic goal is to do the same, to balance the red and  
25 blue group on everything else that you know about. And so



1 they did that and then you compare the rate now you're  
2 re-weighted the data so the rates change a little bit when  
3 you've down-weighted some women in the red group or  
4 up-weighted in the blue you're down-weighting the weight you  
5 put on that outcome also and you get a new comparison and  
6 that's what led to their final reported result and it dropped  
7 I think to, well, I'm not sure it's here, but 1.09 as my  
8 memory. So, it dropped again, just a small fraction closer to  
9 one.

10 Q. Now, Dr. Jewell, you did something at the stage of  
11 depression restricted, well, first of all, does Huybrechts  
12 supply the various variables and data that they used to create  
13 their propensity score analysis?

14 A. No. They don't allow you to do that. They tell you  
15 about it, but you'd have to have the raw data to be able to  
16 change it yourself or re-weight things a little bit  
17 differently. All of these adjustment for confounding little  
18 differences that's why I'm not particularly caring about that  
19 odds are that they [indiscernible] odds ratio being 1.0 or .98  
20 because you put in another variable it will make a little  
21 shimmy to it and change it slightly, but I can't do that even  
22 if I wanted to with the Huybrechts data because you need the  
23 original massive database and they aren't willing to release  
24 it for good reason.

25 Q. Now, so at the level where you did have information Dr.

1 Jewell, you did something with this group of women in this  
2 slide that would show appeared depression restricted, 11,059.  
3 You did an analysis of those women in particular; is that  
4 right?

5 A. Yes, because the Huybrechts team provided additional  
6 data on that red group that they themselves have deliberately  
7 collected to try and refine the measure of exposure by  
8 counting how many fills of prescriptions they had during the  
9 first trimester.

10 Q. So, if I'm understanding correctly Huybrechts original  
11 data in the paper that we did pull up and that's in the  
12 Court's binder actually provides data about these 11,000 women  
13 that include a particular whether or not these women filled a  
14 prescription during the first trimester or filled two or more  
15 prescriptions during the first trimester or filled none; is  
16 that correct?

17 A. So, that is correct. So we just talked about adjusting  
18 for confounding. We want to make the red women and the blue  
19 women as alike as possible on all these other factors and then  
20 they're only different, because one was exposed to Zoloft and  
21 the other was a depressed woman, but not exposed even to any  
22 SSRI.

23 But the blue women are -- the whole point of that  
24 re-weighting with having to measure 200 variables is because  
25 you don't believe the red women are really alike enough so

1 what --

2 Q. You don't believe the red and the blue in this analysis  
3 are alike enough?

4 A. Well, that's the point of doing that additional  
5 adjustment that took her from 1.16 to 1.09 that was that whole  
6 massive 200 variable stratification stuff, propensity score  
7 analysis. And okay, that's complicated you can't reproduce  
8 it's difficult and it's done because of this concern that the  
9 red and the blue women are still subtly different on other  
10 characteristics, I understand that.

11 But why Huybrechts themselves provided the data is you  
12 could take the red group and now compare red with red. In  
13 other words two different kinds of Zoloft women. So, you're  
14 taking the --

15 Q. [Indiscernible] that red?

16 A. Yes, it's all read in this case going back to the  
17 previous slide. These are the -- if you add these up these  
18 are the original 11,059 so if you flash forward again, take  
19 those 11,059, now they're all read and they're all homogeneous  
20 to the extent they were all suffering from a diagnosis of  
21 depression. They were all taking Zoloft to treat the  
22 depression. They all got pregnant, but then as we talked  
23 about Jimenez-Solem some of them behaved differently during  
24 the first trimester with regard to their Zoloft prescription  
25 than others and that's what this breakdown of this 11,000 is.

1 Some of them didn't refill the prescription.

2 Now, where he just talked about to be exposed in the  
3 Huybrechts data, you might have had a pill that took you one  
4 day into conception. That would count you as exposed, or two  
5 or three whatever.

6 If you didn't fill a prescription at that point you  
7 were really not very exposed if you only had pills for one  
8 day, in fact we don't even know if you took them, but, even if  
9 you did, according to your prescription you could only have  
10 taken them for one day, because we didn't refill the  
11 prescription.

12 So the red group here now is a group that is much less  
13 likely to be as heavily exposed to Zoloft to doing the  
14 critical first trimester than the blue group. We don't know  
15 for sure, no one does who took what on which day but as I just  
16 pointed out if you were exposed because you had pills that  
17 took you day beyond conception and then never fill the  
18 prescription you'll be in the red group.

19 If you were a woman who had pills on the prescription  
20 prior to conception that took you one or two days into  
21 pregnancy and then you refilled you'll be in the blue group.  
22 So this provides a very natural counterfactual experiment,  
23 meaning these women were all identical, we couldn't separate  
24 them up to the moment of conception. They were depressed,  
25 they got pregnant, they were on Zoloft, they were on Zoloft

1 enough most recently they had enough pills to take them up  
2 until conception and a little bit beyond and then some of the  
3 women stopped filling the prescription and some didn't and  
4 that's the red and the blue comparison here. As I said, shark  
5 of randomization which we can't do. This is actually the most  
6 natural homogeneous comparison possible. We're not bringing  
7 in women who never saw Zoloft. We're not bringing in women  
8 who aren't depressed. We're not bringing in women from  
9 different countries. These women were all indistinguishable  
10 as a group until the moment they conceived and then for  
11 whatever reason something happened to separate them into red  
12 and blue. Most of them kept taking Zoloft, 8,600, but 2,442  
13 and Huybrechts had separated out the data by these two  
14 categories in her data supplement in her paper.

15 Q. So what did you find Dr. Jewell when you ran this  
16 analysis?

17 A. Right. So this is a natural experiment. I always was  
18 curious because of doing this is the big point of  
19 Jimenez-Solem to do this natural comparison. He is the only  
20 other study I have the data to do this and you see a 90  
21 percent, 87 percent to be precise increase in risk of cardiac  
22 defects in the blue group compared to the red group.

23 Q. Now --

24 A. So, the ones who continued taking it to the paused  
25 group and that's statistically significant. So that's not

1 explainable by chance. Now, this isn't torching. I didn't  
2 try 15 of these kinds of analyses. I didn't try of these  
3 kinds of analyses. I went from Jimenez-Solem I read  
4 Huybrechts I said you can do exactly the same thing as  
5 Jimenez-Solem did in Huybrechts, she provided the data to do  
6 this crudely and I did it. In fact that's the whole point of  
7 trying to refine the exposure and get groups of women and  
8 restrict a depression diagnosed women and then now to all  
9 women, all these women taking Zoloft that's the whole point of  
10 this analysis in it's as powerful a comparison as you can get,  
11 but it doesn't present itself very often, only in  
12 Jimenez-Solem with its limitations and in Huybrechts with its  
13 limitation are you allowed to do this kind of comparison.

14 Q. Now, Dr. Jewell, because exposure in Huybrechts means  
15 any pill that could, that overlaps with the first trimester,  
16 doesn't that mean that the woman who fills a prescription for  
17 Zoloft in the second month of her pregnancy ends up  
18 being "exposed" even under your analysis?

19 A. Yes, Mr. Cheffo made a big point this morning that this  
20 is a ludicrous comparison, maybe I'm overstating how he didn't  
21 like it, but by [indiscernible] these are both exposed. How  
22 can you compare exposed and exposed?

23 But I just point out they're not the same, one was  
24 continually refilling. Some women in the blue group would  
25 fill their prescription twice in the first trimester, some

1 only once. The one in the red never refilled it so, they're  
2 not the same. Now, he's right, some of those red people may  
3 very well be exposed and they might have been exposed at the  
4 critical moment of organogenesis. I accept that, I can't  
5 separate them out because no one was watching the women, I  
6 don't know that. If they were hypothetically exposed at the  
7 critical moment, what would that do to the rate of defect if  
8 there is an association? It would increase the rate; right?  
9 Because they'd be exposed to Zoloft at the critical moment.  
10 I've treated them in this analysis as unexposed.

11 If in fact they weren't exposed the 1.87 would go up.  
12 So if Mr. Cheffo would provide the information from Dr.  
13 Huybrechts we know it's impossible, but if we hypothetically  
14 get this information and get rid of those exposed people from  
15 the red group the odds ratio would be even higher, that's  
16 obvious and demonstrable.

17 So, I don't have the same and in fact, I said this in  
18 the report and in my deposition, that's why that didn't bother  
19 me as much as you might think that the red group might have  
20 some people who in fact took the separate, you know, they took  
21 pills longer than their prescription or they took them through  
22 the critical period, because it would only -- if I could get  
23 rid of them, it would only make it worse for Zoloft, so I'm  
24 being conservative here in this comparison if that was really  
25 their concern.

1 Q. So, Dr. Givens filed a report in this case, Dr. Jewell  
2 where he took some umbrage of the fact that first he agreed  
3 that this information is available in the Huybrechts study and  
4 this is a quote on the slide called Givens Challenge his  
5 paragraph 23 from his report said, "Professor Jewell has also  
6 not conducted his new analysis separately for women who filled  
7 two or more prescriptions," and that data is available in the  
8 same table and he describes it this would guarantee a refilled  
9 prescription during the first trimester. Do you think that's  
10 a good idea?

11 A. Well, it's fine to do that. I did it by anyone filling  
12 at least one, so I included people who only had one filled  
13 prescription in my blue group, the exposed group. He wanted  
14 me to go even further by saying if you're really going to do  
15 this the way he would like, he would like it to be more  
16 definitive in the blue group now and say let's get rid of the  
17 ones who only filled one prescription, let's take those who  
18 fill two or more -- to use his words guaranteed that their  
19 exposed.

20 Q. What's that look like?

21 A. So, I did it of course after I saw his report and it's  
22 an identical result to within .01, as 1.88. This is now in  
23 the blue group only looking at women who had prescriptions  
24 leading up to pregnancy, filled a prescription at least twice  
25 during the first trimester as compared to the red women are



1 still the same. They had drugs taking them up until  
2 conception but never filled a prescription so it's a more  
3 clean if you want, I've got rid of the middle group here where  
4 they're, you know, what's with those women that filled it  
5 once? And it's exactly the same result and even though I've  
6 thrown away some data here it's still significant. So,  
7 there's clearly a difference between those women, blue women  
8 the continued users compared to the women who are not filling  
9 prescriptions during the first trimester.

10 Q. So if we say that this, the blue women have filled two  
11 prescriptions in roughly a three-month period for the first  
12 trimester of pregnancy that would exclude then women who might  
13 otherwise have been in that group who didn't start their  
14 prescription until third month of pregnancy; right?

15 A. Yes, I think his concern, I haven't talked with him and  
16 he didn't explain it, but I think the concern might be that  
17 you would have a woman who had enough pills to take into the  
18 first few days postconception stopped and then filled a  
19 prescription a day before the end of the first trimester that  
20 would count in my first analysis as one prescription fill and  
21 that particular woman wouldn't have been exposed in the blue  
22 group even though I called her as more exposed. So, you said  
23 let's get rid of that by doing the two. And of course it  
24 gives you the same results, by the way the bias in that if one  
25 could remove from the analysis from the blue group women who

1 weren't truly exposed if there are really some women in that  
2 blue group who are not exposed and therefore at no risk it  
3 would only make the odds ratio bigger again. So these two  
4 concerns, these two challenges haven't been thought through.  
5 They actually would make it worse for Pfizer if those women  
6 were to be removed if we had more definitive data. So, I'm  
7 actually here being conservative with regard to this  
8 comparison.

9 Q. Now, to be fair Dr. Jewell, one of the criticisms of  
10 this analysis that we've heard from Pfizer is well, look Dr.  
11 Jewell we know there was a stratification of the crude and  
12 then they did a depression restricted group which is what you  
13 used for your data, but in the Huybrechts study they went down  
14 to propensity scoring and even two levels of that if you look  
15 at the supplement. This is not adjusted for those propensity  
16 scoring Dr. Jewell.

17 A. That is correct and that was the content of -- I  
18 discussed that at deposition, I couldn't do that because that  
19 would require me having the individual level data to have  
20 those variables to adjust for confounding at this point and  
21 Dr. Huybrechts and I in that brief e-mail exchange discussed  
22 this point and as I said, that's exactly why I need the data  
23 or have you guys run it for me if you want, I don't have the  
24 data in my hands I've done that before where someone will do  
25 it and I'm blinding, so there's no confidentiality. That's to

1 take care of that loose end, there's no adjustment for that  
2 additional confounding.

3 Two reasons I'm not -- I'd love to do it and I asked if  
4 I could and I've been, I think the last message from Krista  
5 Huybrechts was we're talking to our team about doing it for  
6 me, basically. So, I think she -- maybe that will come  
7 through, but why I'm not that -- I'd live to see the results  
8 why I'm thought that concerned to be that I'm misrepresenting  
9 anything here is one, is already these groups of women are  
10 much more homogeneous than the group we -- that they applied  
11 their propensity score to which included all women who had a  
12 depression diagnosis but had never seen a -- never come within  
13 an arm's length of an SSRI. So that's a more heterogeneous  
14 group but this group as I said these women were  
15 indistinguishable until the moment conception happened so  
16 there's likely far less difference between them than there  
17 would be in more heterogeneous groups. So, confounding won't  
18 make as big a difference and two, when you look at where there  
19 was more heterogeneity in the original mean or comparison of  
20 Huybrechts and they did that adjustment for confounding it  
21 reduced as you saw from 1.16, I think the 1.09. So, it  
22 changed the odds ratio by .07 or a few percent.

23 Now, if you applied said well, we don't know how much  
24 difference adjusting for confounding of these results would be  
25 anyone like me, any statistician is going to say, well, what

1 plausible, what kind -- given that I can't do it today what's  
2 plausible about the impact of confounding? I saw 4 percent  
3 effective confounding on the more heterogeneous case even if I  
4 applied the 4 percent to the 1.88 that's going to reduce it to  
5 1.7, it's not going to reduce it to one, so this is just not  
6 plausible that confounding can explain this result given what  
7 we know about confounding in the entire data set that  
8 Huybrechts is provided and when you see the size of the effect  
9 here.

10 Q. So, Dr. Jewell to summarize on this slide entitled  
11 Givens Huybrechts Givens Reanalysis you found it statistically  
12 significant one point I think you'd say that's 1.9 or 1.88  
13 increased risk in a group of women who were all on Zolofit at  
14 or around conception and all were depressed?

15 A. And all took -- yes. That's the whole group. They're  
16 all exactly the same at that point still. And then the blue  
17 group is those women went on to take -- fill prescriptions at  
18 least twice during the first trimester and the red group never  
19 filled a prescription.

20 Q. Did you create any of this data or was this data  
21 available? Did you [indiscernible]?

22 A. This data for the crude comparison is all available in  
23 the Huybrechts paper.

24 Q. And Huybrechts supplied it because part of what she  
25 discussed was we looked at -- we were concerned about our pill

1 counting methodology so we also tested that to see if taking  
2 one or more prescriptions during the first trimester as  
3 compared to our pill count it changed the results or taking  
4 two or more it even changed the results. So, this was part of  
5 their methodology.

6 A. It was part of their methodology, part of what they  
7 called their sensitivity analysis. There they focused on the  
8 blue groups here and compared them back to the unmedicated  
9 depressed women and it never occurred to them to do this  
10 comparison and when I was interacting with Dr. Huybrechts  
11 since earlier this year when she asked me to explain it, she  
12 got it finally and said yes, I think this is an interesting  
13 possibility. Let me get back to my team with it I'll be able  
14 to give you what you want which is the confounded adjusted  
15 version of what I did.

16 Q. And that's what she wrote in this e-mail; is that  
17 right?

18 A. Right. Yes. This is where she says, it's an  
19 interesting possibility our agreement doesn't permit to share  
20 the data with me why don't I speak with others and assess what  
21 we can do from our end. So I'm very hopeful they'll do that  
22 so I don't have to have this discussion about that 1.9 how  
23 much it really changed, let's just do the analysis.

24 Q. And what does she mean when she says it will be  
25 surprising or what is your understanding? The scientist, what

1 she's trying to communicate when she says it'd be surprising  
2 and this an e-mail from Dr. Huybrechts to you dated July 12,  
3 2015. What's your appreciation of what she means when she  
4 says, it would be surprising for post hoc subgroup analysis  
5 such as the one you described to supersede all other  
6 prespecified analysis?

7 A. I actually didn't quite know what she meant by that,  
8 because she's misinterpreting what I was trying to do.

9 There's an e-mail I sent immediately back to this one saying I  
10 have no intention of the superseding, your main results they  
11 are very interesting in themselves, they're all in my report,  
12 but this is a particularly interesting comparison and now I'm  
13 using not just my words, I'm using her words too. And it's  
14 interesting in a way I tried to explain to her because we have  
15 the results from Jimenez-Solem that aren't identical, but are  
16 trying to achieve essentially the same thing and they're the  
17 only two papers that allow us to get this very homogeneous  
18 comparison of Zolof users depending on and comparing whether  
19 those who kept using it versus those who didn't.

20 Q. And that's what led you to do a meta-analysis of your  
21 own in your report; is that right?

22 A. Right. So the Jimenez-Solem analysis that we discussed  
23 earlier comparing their non-paused with the paused group of  
24 users was not statistically significant. It's still a sizable  
25 risk there's some reason to believe that may be understated

1 for reasons we've discussed already, but now we have  
2 Huybrechts. They're not identical. The other hand they're  
3 giving very similar pictures and if you of course put the two  
4 together it becomes now highly significant. Your now  
5 comparing in both cases people who took Zoloft by some  
6 definition throughout the first trimester with women who used  
7 to take Zoloft, but didn't given that proviso that  
8 Jimenez-Solem didn't -- couldn't quite give us that, but --  
9 and so that's -- these are very similar results there's no  
10 heterogeneity here as you can see at all, so.

11 Q. And Dr. Jewell, we're looking at a slide that's  
12 Meta-Analysis Huybrechts and Jimenez-Solem and this describes  
13 the results and of combining in a meta-analysis context  
14 Huybrechts and Jimenez-Solem and the output which shows an  
15 increased risk of 1.8.

16 A. Right and I just need to stress again, this is in some  
17 sense the most natural comparison you would want, because all  
18 of the other studies we struggle with this who do we compare  
19 the SSRI users or Zoloft user specifically with? What's the  
20 right comparison group of women and that has been a big  
21 discussion in the literature including this whole that spawned  
22 this idea of confounding by indication.

23 So, both Jimenez-Solem and Huybrechts went and some  
24 others have gone one step towards resolving that by looking  
25 only at women with a diagnosis depression. I just took it a

1 very natural next step. That's why I thought it was  
2 interesting Pfizer urged me to publish this at trial. I've  
3 now tried to, but I can't, I don't feel comfortable doing this  
4 without -- I don't want to use Huybrechts' data and take it  
5 and published on my own. I prefer to have something as a  
6 joint publication.

7 THE COURT: Did I just hear right? Did you say  
8 Pfizer urged you to publish?

9 THE WITNESS: Well, they asked me why, if I  
10 thought it was so important why had I not asked to, why had I  
11 not written a paper so, I took their advice and said, yes,  
12 better do that. And that's what led to the e-mail to  
13 Huybrechts.

14 BY MR. ZONIES:

15 Q. You mentioned heterogeneity when you did this  
16 meta-analysis, Dr. Jewell was there heterogeneity that was  
17 evident as there was in miles and the other meta-analysis?

18 A. No. You could see that with the naked eye there. That  
19 1.9 and 1.6 are given those confidence intervals you can't  
20 statistically distinguish between them so there is no evident  
21 heterogeneity here. So it makes sense to average in this  
22 case, I mean, here, you're averaging two, so you can either,  
23 whatever your fancy you can look at the two results separately  
24 if you want to say well, the Huybrechts is just significant I  
25 forgot what the P value was flora bound is 1.1. It's a little



1 bit more significant when you combine the two studies which is  
2 the point of meta-analysis, of course.

3 Q. And how many studies were in wang; do you recall?

4 A. In wang?

5 Q. Yes.

6 A. Three.

7 Q. Throughout your report Dr. Jewell, do you also spend a  
8 significant amount of time looking at other confounding  
9 factors and potential biases that may have effected these  
10 results beyond just detection bias and confounded by  
11 indication?

12 A. Yes. As I've already alluded to several times there's  
13 this concern that women in the comparison group may not be  
14 identical to women in the exposed group on a bunch of  
15 behavioral characteristics, like smoking, obesity and so on  
16 and so -- and this is an observational study so that it's not  
17 resolved by randomization of exposure as it would be in a drug  
18 trial. So, here you've to work hard at this and most of the  
19 authors tried depending on the quality of their data to do  
20 this at various stages so we do see how much the results  
21 change as these authors were wrestling with this adjustment  
22 for confounding.

23 Q. And the last one is other unknown factors residual  
24 confounding, can you describe what residual or unmeasured  
25 confounding means?

1 A. Well, that essentially means when an author or team,  
2 research team has tried everything they have measurements on  
3 to get rid of these possible differences between the exposed  
4 and unexposed women. They might still worry because there's  
5 no randomization that the difference in the risks let's say  
6 for cardiac defects that still exists might be due to  
7 something we didn't measure and that's what people refer to as  
8 unknown or residual confounding.

9 And of course any observational study from the  
10 beginning of time always has the possibility that there's some  
11 unknown factor. But we're not completely powerless as  
12 statisticians, because as I indicated earlier, we know for  
13 example to get rid of that 1.9, you need a fairly sizable  
14 effect on the outcome cardiac defects that you don't know  
15 about to be able to explain it away. So, there's concern  
16 about it, but there's also -- we're not completely hamstrung  
17 by we're able to think about what the potential impact might  
18 be of an unknown confounder.

19 Q. And we'll just touch on Bradford Hill factors, Dr.  
20 Jewell you mentioned that strength of association was the  
21 first factor. What did your review of the data show with  
22 regard to strength of the association?

23 A. Well, strength of the association is the idea it's  
24 related to confounding that the stronger the effect you see  
25 the less chance that something unknown could be -- dealing

1 with. So if you have an odds ratio of 1.1 or a  
2 [indiscernible] risk of 1.1 then it's not so hard for an  
3 unknown confounder to wipe that out, because it only needs to  
4 have relative risk of 1.1 and there might be things around  
5 that raise the risk of a cardiac defect by 10 percent that we  
6 don't yet know about. A lot of cardiac defects we don't the  
7 cause so that's possible, but when you get up to two or three,  
8 it becomes much less likely that something you don't know  
9 about is completely going to explain away that result. So,  
10 that's why in Hill's criteria strength of association is  
11 important. It is particularly if you're dealing with making a  
12 policy change. You want to be reasonably sure. So the  
13 stronger the association the less chance it's spurious.

14 Q. And again is this just oh, you look at the numbers and  
15 you go oh they are this? Or is it well, you know, this I feel  
16 is stronger the Huybrechts analysis outcome for a strength of  
17 association is stronger because I've done a very deep dive on  
18 trying to remove all of those confounding factors?

19 A. Well, as I said, the advantage of that analysis is that  
20 you've really done amongst a very homogeneous group of women.  
21 The others don't have that advantage but their very strong  
22 effects. And so there are some very strong effects here that  
23 would concern any of us.

24 Q. Consistency of effects is the second Bradford Hill  
25 factor and on the screen is the bond paper discussing at least

1 those investigators just conclusions that there were  
2 consistent effects for an increased risk of cardiac birth  
3 defects with the use of Zoloft. Is that consistent with your  
4 conclusion as well?

5 A. Yes, the idea here is if you've done an observational  
6 study and you see an effect and you get alarmed and I'll tell  
7 you it happens, it crosses my desk quite a lot, the next --  
8 but then there are other studies and there's no effect if  
9 you've just seen it once that makes you suspicious.

10 So the idea of consistency here is not that you expect  
11 every single result to just come in on the nail, everything is  
12 the same, I wish that it were, I would be -- have a much  
13 simpler job. They come -- they bounce around a bit and we've  
14 seen that in the visual representation.

15 The idea though is, is it just one study? That's  
16 obviously no. Is it just two? No. Is it just three in this  
17 case? No. And so, we've seen enough here to say this is not  
18 just one spurious thing that happened by chance in one  
19 population. That's just -- I'm not just relying on that  
20 myself, other authors constantly state in their paper is this  
21 result consistent with what we know so far. And you've picked  
22 out Bamm [ph] which is in the United Kingdom, I think.  
23 Here's -- well, Pfizer's own epidemiologist characterizes this  
24 consistently positive. They don't mean every study gave the  
25 same result is you can see in what they were report in this

1 paragraph, that's not true but they do see enough to say  
2 there's something consistent going on, it's a tricky English  
3 word, but consistent is is it's not something that just  
4 happened once by chance coincidentally.

5 Q. And we're looking at slide, Dr. Jewell, entitled  
6 consistency Pfizer epidemiologists agree and it's a Pfizer  
7 document in 2014 where Pfizer's scientists conclude that  
8 there's a consistency insistently positive association for  
9 searching the exposure and cardio vascular defects especially  
10 septal defects. And that's something you agree with; correct?

11 A. That's consistent with my opinions, yes.

12 Q. Did you reach your conclusion about this even before  
13 you saw this?

14 A. No. Actually I didn't see this document until the Frye  
15 [ph] hearing.

16 Q. So, it wasn't like you relied upon this to reach your  
17 conclusion, you just saw it's in agreement with your  
18 conclusions?

19 A. That is correct. And to me it's not so much important  
20 what their opinions are it's the methodology that's consistent  
21 that they were doing the same kind of thing, albeit in a  
22 smaller set of studies as was pointed out this morning by Mr.  
23 Cheffo, but the methodology was still the same. You take the  
24 studies, you look at them and you see if there's a consistent  
25 positive association.

1 Q. And the next slide is again the flores plot that we  
2 will have enlarged by tomorrow showing all of their results  
3 and as you've said before part of what you do is look at this  
4 to see the symmetry I think or the asymmetry, I'm sorry --

5 A. Well, first of all it's -- I was going to say it's  
6 effective visually to see all the results on one page. We've  
7 just determined that it's not that effective. So, I  
8 understand that and I can't read it myself and I've got  
9 contacts in. But it does in some sense the blurring may  
10 actually be valuable here, because it's saying what you really  
11 want to get out of this is not the numbers, you know, the fine  
12 detail on the left-hand side, the thick solid line is one.  
13 The number, the relative risks are odds ratio run on the  
14 bottom axis from .1 to 10 equally, because there's an  
15 asymmetry on the axis, so you may -- .1 is the same distance  
16 from 1 is 10. One protects you tenfold, one is tenfold bad,  
17 so that it's balanced that way, so we're not distorting it by  
18 not using a log scale.

19 And then just look at them and say, well, what's  
20 your -- is this completely down the middle? Is it asymmetric  
21 to the right or to the left? Now, we can't do this in the  
22 courtroom, what I always do is if you're struggling, I don't  
23 think there's a single person in this room that really is  
24 struggling with the IP address symmetry, it's pretty obvious.

25 But if you're really are still struggling just turn it

1 upside-down and see if you still feel the same. If you can't  
2 tell the difference whether there's more stuff pushed to the  
3 right, meaning an increased risk than there is to the left  
4 meaning a decreased risk, if the relative risk is one  
5 everything should be sort of balanced on the each side; right  
6 by chance? If you can't tell the difference between this when  
7 you look at it this way and turn it upside-down then I can  
8 sort of say, well, it didn't work for you, you see no  
9 difference. When I do that, when I turn it upside-down I see  
10 that the asymmetry has shifted to the left by my eyes and so  
11 that's what this really represents in a visual way there is  
12 this push to the right rather than the left. Is it absolutely  
13 the same everything single study, I never have seen that and  
14 this is tough but it's not what you expect.

15 Q. And to be fair and we'll see it when it's clearer.

16 This includes repetition of findings within studies.

17 A. It does.

18 Q. In other words certain studies like Jimenez or Coleman  
19 [ph] I think Coleman shows up the most on here; right?

20 A. Well, some of the papers reported more subgroups than  
21 others, but you can do this if you want by taking just the all  
22 cardiac outcomes.

23 Q. So, we talked about this book by Rothman and Greenland  
24 called Modern Epidemiology, are you familiar with this book?

25 A. Yes, and I know two of the authors quite well.

1 Q. And in this book there's this quote about consistency,  
2 because I mean, I suppose I'm a big concern that Pfizer is  
3 going to get up and say, well, all of these aren't significant  
4 you shouldn't look at those which frankly if we were looking  
5 at consistency and only looked at the significant findings  
6 well, heck, we could go home. But you actually look at all of  
7 them including the nonsignificant protective effects; correct?

8 A. Yes, they're important and if there's enough of them  
9 they're going to influence your opinion.

10 Q. And is it consistent your methodology with this  
11 discussed in this book in this [indiscernible] treatise that  
12 it sometimes claims that a literature or set of results is  
13 inconsistent simply because some results are statistically  
14 significant and some are not. This sort of evaluation is  
15 completely fallacious. Even if one accepts the use of  
16 significant testing methods. The results from a set of  
17 studies could all be identical even if many were significant  
18 and many were not et cetera. Is that consistent with your  
19 methodology and the methodology that you recognize as that in  
20 your science?

21 A. Yes, that's generally true. And one of the reasons is  
22 that significance is driven by more than what the truth is.  
23 It's driven by the size of the study and many other things, so  
24 you can have two studies that have really studying the same  
25 population that have the same results one is just not



1 significant because it's not powered enough, it's not big  
2 enough, but does that it doesn't provide any information? No.  
3 You should use all the information and significant results and  
4 nonsignificant results should both be assessed and you've got  
5 to weigh those in your coming to any reasonable scientific  
6 opinion.

7 Q. And if we were assessing consistency and relying solely  
8 upon significant results would there be an asymmetry in this?

9 A. Well, that -- yes, because there are no negative  
10 asymmetry. I would never believe, I would've been surprised  
11 if there were as Mr. Cheffo would also have been shocked if  
12 there had been a significant result on the left, because no  
13 one really believes that the drug is going to protect you from  
14 cardiac defects and if you just studied it enough it would  
15 show up. So, I understand why there isn't any. No one is  
16 surprised at that. But that's one of the reasons why it  
17 would've been unfair to me to Pfizer to ignore the ones that  
18 are somewhat negative. They're negative and they show no  
19 increased risk all albeit they have imprecision attached to  
20 them.

21 Another main reason why you shouldn't just focus on  
22 significance in balancing though studies, those studies are  
23 not all equally good. We haven't talked about that that much.  
24 We've mentioned it, oh, somebody said, Huybrechts is a great  
25 study or Jimenez-Solem is a great study, because it's so big

1 and has so many women. Big studies don't have any guarantee  
2 to get rid of bias. They get rid of -- they help you with  
3 precision; right? But they don't do anything about bias.

4 The largest presidential poll in the history of the  
5 United States protected Dewey would beat Truman; right? And  
6 it was a shock and it was the birth of modern polling, because  
7 people say we -- everyone said Dewey was ahead. It was a huge  
8 poll, but it was biased, because it was subscribers to the  
9 literary digest and they were -- had a particular political  
10 bend.

11 So, big polls if their biased are useless because even  
12 though they get very precise results they don't necessarily  
13 help you. So, we've talking about these studies and the  
14 visualization fails in some regard, because it treats each  
15 line as somehow equally valid other than the sort of  
16 confidence interval. But that's not true, there are some very  
17 good studies in here in my view when you analyze them with a  
18 statistical assessment of bias and there are some rather poor  
19 studies and we -- I could now if you want at some point or if  
20 Pfizer wants I can tell you which ones I think are poor and  
21 why I believe that, what's the objective criteria. But that's  
22 the danger of just putting them all on an equal footing either  
23 in a plot like this it's dangerous to do -- to read something  
24 quantitative in this and it's also dangerous if you just throw  
25 them all in a meta-analysis, because you're not dealing with

1 that at all.

2 Q. Well, and that's a point and that I want to make it  
3 perhaps is my mistake that I want to ensure that everyone  
4 understands, Dr. Jewell, which is you didn't assess  
5 consistency with a flores plot; did you?

6 A. No.

7 Q. When you were doing your analysis?

8 A. No. The flores plot is merely just a way to get all of  
9 the studies on the page so we can talk about them and find  
10 them quickly.

11 Q. And in fact in your paper you go into great detail  
12 about which studies you find strong and why and which studies  
13 you have concerns about and how you would individually assess  
14 those and how you did in fact individually assess those?

15 A. Yes, and that's a very important topic we really  
16 haven't addressed so far today.

17 Q. Specificity or the short-term shorthand term for this  
18 that I don't mind saying is lumping of endpoints and one of  
19 the primary concerns in the original doubt we're hearing in  
20 this case was looking at an endpoint called all congenital  
21 malformations, that's not something you were comfort doing was  
22 it Dr. Jewell? Looking at that endpoint.

23 A. No. I would've, I always prefer to get as specific a  
24 charge as possible, specific in endpoint and one can do it  
25 looking at all malformations but there's a lot more

1 heterogeneity in that clumping than there would be in a  
2 subcategory.

3 Q. And as you described very carefully in your report, you  
4 didn't as we said a number of times -- this quote from your  
5 report at page 17, you didn't independently modify or poll the  
6 endpoints; correct?

7 A. No.

8 Q. And you go into detail in your report again, Dr. Jewell  
9 about how you relied upon the experts in the field including  
10 as we see up on the screen here the EUROCAT European  
11 Surveillance of Congenital Anomalies Association in part on  
12 their choice of classification and grouping and even they say  
13 lumping together heterogeneous sets of anomalies; is that  
14 right?

15 A. Yes. This is -- EUROCAT and their summarizing I think  
16 I actually probably used this quote, because they summarize  
17 while the conundrum that I mentioned earlier when you're  
18 trying to group outcomes that you know are not identical as I  
19 said about lung cancer. Pathologists know they are not  
20 identical but if you get down to two fine a grid, that's their  
21 B there, if you split so finely there are so few cases of this  
22 very fine subgroup that you can't distinguish, there's not  
23 enough information, in fact there would be a tactic to use if  
24 you wanted to get to no statistical significance just get down  
25 to a very fine subgroup. I'll guarantee you no statistical

1 significance. Any study you want, give me now in 30 minutes I  
2 will make a finer subcategory and the statistical significance  
3 will go away. Would you believe this? No. Right, that's  
4 just Machiavellian.

5 The other side is, oh, if you put too many together,  
6 let's go the opposite direction. If you put too many together  
7 and you said let's do all congenital abnormalities now you  
8 really are talking about different organs of the body that are  
9 effected at different times during pregnancy and you may be  
10 diluting any specific association so every expert has to --  
11 what is it they say strike the balance here. And I would've  
12 been faced with that where I left on my own, the balance I  
13 struck was to use the balance struck by the original  
14 investigators. So I didn't try and add something into cardiac  
15 or I didn't do anything they didn't do.

16 Q. And the last criteria or last viewpoint of Bradford  
17 Hill biological plausibility. And Dr. Jewell do you agree  
18 with this quote, I'm showing a quote from the reference manual  
19 on scientific evidence 3rd at 604 that says when biological  
20 plausibility consists it lends credence to an inference of  
21 causality, because as it says, just above that biological  
22 plausibility is not an easy criterion to use and depends upon  
23 existing knowledge about the mechanism. So, when it does  
24 exist, it actually means something good.

25 A. It's important, in fact, this is of course the one area

1 I'm not an expert as had been pointed out. I'm not a  
2 cardiologist. I'm not an expert on perinatal birth defects.  
3 I'm a statistician. So, I'm an expert at looking data that  
4 other people have defined and categorized and put together.

5 They're not so good at what I do and I'm not so good at  
6 what they do. So, when it comes to biological plausibility, I  
7 personally cannot, I do not study the biological mechanism  
8 during organogenesis. I have to rely on other biologist in  
9 this case. I have consistency, that's a statistical issue.  
10 Strength of an association statistical issue. Hill was a  
11 statistician. Biological plausibility does it make sense if  
12 the flowers in your garden are red that you suffer from a  
13 birth defect? Probably not. There's no biological  
14 plausibility unless somebody comes forward, we've said oh  
15 there's an allergen in it, and then there's a biological  
16 mechanism, but you have -- if there's no biological mechanism  
17 known to the scientist who are experts that weakens the case I  
18 think of causality substantially.

19 Q. And here you've found, you're relying upon the experts  
20 in this case that indeed there was a biologically plausible  
21 mechanism?

22 A. Yes, I think there's a bunch of evidence that's not  
23 evidence that I have to take other expert's opinions.

24 Q. Well, and one of the issues Dr. Jewell is -- and is  
25 this about the difference between SSRI drugs and your

1 biological mechanisms in fact. So when you did the Huybrechts  
2 analysis, subanalysis for Zoloft you came up with a  
3 statistically significant [indiscernible] almost double  
4 [indiscernible]. In your Prozac work did you also do a  
5 similar analysis with the Prozac data from Huybrechts?

6 A. Yes, I did. I did exactly the same analysis for  
7 Prozac, I actually did it for Paxil too just to get a sense of  
8 what the data was saying. I testified to that when I was  
9 deposed on Prozac, I presume Pfizer has a copy of that. I  
10 testified it when Pfizer deposed me on a second deposition, so  
11 I have said many times that I have done it, it's not true that  
12 I have never done it for Prozac.

13 It's not that I haven't done it, Prozac is a different  
14 drug as is Paxil, so it's just different. But I have done the  
15 calculations and they've seen -- everyone in this room whose  
16 interested has seen my analysis of those results.

17 Q. But Dr. Jewell, you didn't include those results in the  
18 Prozac report and Pfizer in their opening said oh, well,  
19 that's because he didn't like those results. Is that why you  
20 didn't include those in your Prozac report?

21 A. No. And those results by the way were in the e-mails  
22 to Krista Huybrechts, so I know everyone has them now where I  
23 was trying to point out that let's do the -- excuse me --  
24 let's do this analysis of like with like that we talked about,  
25 the pause and the non-pause. I didn't want to write

1 necessarily only Zoloft and then be criticized why Zoloft.  
2 Let's do it for all of the ones that we have data which does  
3 include Prozac and Paxil. And those results are in those  
4 e-mails and then of course you have to address in the case is  
5 the half-life of drug itself and Zoloft has a shorter  
6 half-life than Paxil or Prozac, so when you stop taking pills  
7 in a sense you don't fill the prescription, we don't know what  
8 the woman is doing, but if there's any left it's not going to  
9 be as much in their system a week later or two week later as  
10 it would be for Paxil and Prozac. That limits the value, you  
11 know, we remember just struggling, I've been criticized  
12 already today about, well, they're all exposed, you can't  
13 really tell the difference well, the best chance of telling a  
14 difference with Zoloft and a much more difficult task with  
15 Prozac and Paxil and I was aware of that because of the  
16 half-life properties of the drugs.

17 Q. How do you feel about being called a situational  
18 scientist?

19 A. Well, people call me lots of things. You know in some  
20 senses all science is situational. You don't treat dogs and  
21 cats the same way. If they have a thrombosis you treat the  
22 dog differently from a cat. It's situational, it makes sense  
23 to me. Well, I'm a statistician. When you see the same  
24 question let's say in this case Prozac or Zoloft do they cause  
25 cardiac birth defects, it's the same question, but their



1 different drugs that -- what's important to me as a  
2 statistician is what does the data say, so I have to look at  
3 the data separately. I'm not going to say oh, Prozac causes  
4 birth defects as I think it does in Prozac or vice versa. Or  
5 even if I believed one of them didn't cause it, I have to --  
6 I'm trained to tell you what the data says and not play games  
7 and not let it be influenced by my opinions or not, I have no  
8 interest personally on taking one side of this, partly because  
9 I'm involved in many -- one of the statistician's job is to  
10 have to be involved in many of these questions simultaneously.  
11 I've got about four in my head right now where I'm thinking  
12 does this drug cause this problem or not. And in one of them  
13 I think it doesn't I'm not going to tell you which one. And  
14 in three, I think --

15 Q. Well don't tell them.

16 A. Well, they don't care. It's not their drug. And  
17 three, I think it does, but I don't, I can't afford to have a  
18 stake in each of these four decisions, I just take the data,  
19 what I enjoy and what I find satisfying as being trained to do  
20 well is to look at the data and tell you on either side this  
21 is what the data is saying. That's situational in the sense  
22 that the data is different for different situations. But I  
23 certainly don't appreciate the idea that I would just change  
24 my opinion and the data says the same just because there was  
25 some vested interest. I have no entrust in the outcome

1     whatsoever from that perspective.

2     Q.     Were you ever hiding from the difference between those  
3     two?

4     A.     No.   And in fact in my deposition on Zolofit I begged  
5     the deposing attorney to be able to discuss with him Prozac  
6     but he would not discuss Prozac with me during my deposition.

7     Q.     Thank you for your time today Dr. Jewell.

8             MR. ZONIES:   Your Honor.

9             THE COURT:   That concludes your examination and  
10    we'll start with cross-examination in the morning.   We'll  
11    start at 10:00 tomorrow and I think I don't need a board I'm  
12    just asking for a 11 by 14 size.

13            MR. ZONIES:   Understood.

14            THE COURT:   Okay?   So it should be something  
15    easy to do.   All right?

16            MR. ZONIES:   Appreciate that.   Thank you.

17            THE COURT:   Thank you.   Have a good evening.

18                           -   -   -

19                           (Whereupon, the proceeding was concluded  
20                           at 5:21 p.m.)

21                           -   -   -

22

23

24

25

C E R T I F I C A T E

I do hereby certify that the aforesaid hearing was transcribed by me from an audio recording to the best of my ability; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof.

WITNESS my hand and official seal this \_\_\_\_ day of \_\_\_\_, 2015.



Janine Thomas  
Notary Public

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